

Message Text

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21

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 ISO-00 OES-05 MED-03 /047 R

66615

DRAFTED BY DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY OES/SCI/BMP: MBEAUBIEN

DHEW/OIH/MACODDING

EUR/NSC-IG:JROUSE (INFO)

ARA/NSC-IG:RJBLOOMFIELD (INFO)

EA/K:HNEWSOM (INFO)

EA/ROC:KWEAVER (INFO)

----- 033907

R 292204Z NOV 74

FM SECSTATE WASHDC

TO AMEMBASSY SANTIAGO

AMEMBASSY TAIPEI

AMEMBASSY COPENHAGEN

AMEMBASSY SANTO DOMINGO

AMEMBASSY BONN

AMEMBASSY ROME

AMEMBASSY SEOUL

AMEMBASSY MEXICO

AMEMBASSY MADRID

AMEMBASSY BERN

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E.O. 11652:N/A

TAGS: ETRD, EIND, TBIO, CI, TW, DA, DR, GW, IT, KS, MX, SP, SZ

SUBJECT: RECALL OF MEDICAL DEVICE - FLUIDIC VENTILATOR.

1. FDA ADVISES THAT THE OHIO ANESTHESIA VENTILATOR (FLUIDIC), (NO MODEL NUMBER) REFERRED TO BUT NOT LABELED AS OHIO FLUIDICALLY CONTROLLED ANESTHESIA VENTILATORY, MANUFACTURED BY OHIO MEDICAL PRODUCTS, A DIVISION OF AIRCO, INC., 3030 AIRCO DRIVE, MADISON, WISCONSIN 53701 REQUIRES IMMEDIATE MODIFICATION FOR SAFE AND EFFECTIVE USE. VENTILATORS WITH THE FOLLOWING SERIAL NUMBERS ARE TO BE MODIFIED: AAEA00001 THROUGH AAEA00476 AND AAEB00001 THROUGH UNCLASSIFIED

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AAEB01125. THE FOURTH CHARACTER IN THE ABOVE SERIAL

NUMBERS REFER TO THE YEAR SHIPPED. A - 1973, B - 1974. MANY OF THE 1973 SERIAL NUMBERS BETWEEN 1 AND 476 -DN THE 1974 SERIAL NUMBERS BETWEEN 1 AND 1125 WERE NOT USED BY THE MANUFACTURER DUE TO CANCELLATION OF WORK ORDERS. HOWEVER, APPROXIMATELY 800 UNITS WERE DISTRIBUTED BEGINNING IN JANUARY 1973 TO MEDICAL DEVICE DEALERS (17 PERCENT) AND DIRECTLY TO HOSPITALS (83 PERCENT). SINCE THIS DEVICE IS A LONG TERM USE ITEM ALL OF THE ESTIMATED 800 UNITS WOULD MOST LIKELY STILL BE IN USE.

2. THE REASONS FOR THE RECALL ARE AS FOLLOWS:

A. A MANUFACTURING ERROR OCCURRED CAUSING THE VENTILATOR BELLOWS EXPIRATION FLOW RATE VALVE TO BECOME INOPERABLE. MANUFACTURING SPECIFICATIONS CALL FOR THIS VALVE TO BE GLUED IN PLACE. THE VALVE ON THE UNITS UNDER RECALL WERE ASSEMBLED WITHOUT GLUE. IN SEVERAL CASES THE VALVES BECAME LOOSE AND MOVED OUT OF POSITION. THIS CAUSED THE VENTILATOR BELLOWS TO STOP CYCLING IN THE CLOSED POSITION. THIS POSITION PROVIDES AN INSUFFICIENT RESERVOIR FOR GASES EXHALED FROM THE PATIENT. SEVERAL INSTANCES OF TENSION PNEUMOTHORACES HAVE OCCURRED AS A RESULT OF PRESSURE FROM GASES FLOWING INTO THE PATIENT FROM THE ANESTHESIA MACHINE WITH NO RESERVOIR AVAILABLE FOR RELEASE.

B. A SECOND PROBLEM INVOLVES THE GAS EVACUATOR. THE EVACUATOR IS A VENT VALVE WHICH ALLOWS FOR THE ESCAPE OF THE ANESTHETIC GAS MIXTURE WHICH IS IN EXCESS OF THE AMOUNT WHICH CAN BE UTILIZED BY THE PATIENT. ONE INSTANCE WAS REPORTED WHEREIN GASES INTENDED FOR THE PATIENT ESCAPED DUE TO A CROSS THREADED SCREW CAP, WHICH TIGHTENS THE GAS EVACUATOR DIAPHRAGM.

3. FOREIGN CONSIGNEES AS FOLLOWS:

INDUSTRIAS CHILENAS DE SOLDIDURA, CAMINO A MELITILLA NO. 7050,
SANTIAGO DE CHILE, CHILE
MR. P. S. HSIAO, PRESIDENT, SHENG TUNG DEVELOPMENT CO., LTD.,
P.O. BOX 451, TAIPEI, TAIWAN
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DMECA A/S, ISLEV DALVEJ 221, DK-2610, RODOVRE, COPENHAGEN,
DENMARK
CALMET A.A., CENTRO COMERCIAL NACO NO. 1, SANTO DOMINGO,
DOMINICAN REPUBLIC
MR. MANFRED HOYER, CARL A. HOYER, 28 BREMEN 1, PARKALLEE 44,
WEST GERMANY
DR. RENZO MATTEI, CORALMA S.A.S., CASELLA POSTALE 773,
16128 GENOA, ITALY

ASIA SCIENCE AND CO., I.P.O. BOX 1250, SEOUL, KOREA
REPRESENTACIONES MEDICO TECHNICOS, MAZATLAN NUMBER 83,
MEXICO D.F., MEXICO
MR. JOSE GUIDO, GUIDO RAYOS X, ALVAREZ QUINTERO 2, MADRID 4,
SPAIN
LAUBSCHER AND CO., LTD . POSTFACH 4001, GEGRUNDEZ 1896,
RHEINSPRUNG 5, BASEL, SWITZERLAND

4. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
ASCERTAIN WHETHER OR NOT THEY ARE FAMILIAR WITH DETAILS OF
RECALL AND NECESSITY FOR MODIFICATION OF SUSPECT
FLUIDIC VENTILATORS.
INGERSOLL

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Message Attributes

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Decaption Note:
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Disposition Approved on Date:
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Disposition Case Number: n/a
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Disposition Event:
Disposition History: n/a
Disposition Reason:
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